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K121112
PG. 1 OF 2

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Endoscopy

510(k) SUMMARY, PER 21 CFR 807.92

SEP 12 2012

510(k) Owner/Sponsor:	Stryker Endoscopy
Address:	5900 Optical Court San Jose, CA 95138
Establishment Number:	2936485
Telephone Number:	(408) 754-2701
Contact Person:	Kevin Potgieter, RAC; Senior Regulatory Affairs Analyst
Email Address:	kevin.potgieter@stryker.com
Proposed Device:	Stryker Video Ureteroscope
Common/Usual Name:	Flexible video endoscope with video processor
Product Code:	FGB
FDA Regulation Number:	21 CFR 876.1500 - Endoscope and accessories
Device Classification:	Class II
Predicate Device:	Olympus Video Ureteroscope, NTSC
Common/Usual Name:	Flexible video endoscope with video processor
Product Code:	FGB
FDA Regulation Number:	21 CFR 876.1500 - Endoscope and accessories
Device Classification:	Class II
Premarket Notification:	K033651

Device Description

The Stryker Video Ureteroscope is a flexible ureteroscope with a video sensor mounted on the distal tip, which provides the user visualization of the anatomy of the kidney and other urological structures. The bending section is controlled by the user with an articulation lever, to provide control of the position of the sensor. An integrated working channel provides the user the ability to introduce diagnostic or therapeutic instruments into the operative site. A light emitting diode is mounted internally in the handle and is connected to the light fibers that are integrated into the scope, which emit light from the distal tip of the scope, providing illumination of anatomy. The Video Ureteroscope is powered and controlled by a console, which also provides video output to displays, capture devices, and other accessories.

Intended Use/Indications for Use

The Stryker Video Ureteroscope is designed to be used with a Stryker video system, monitor and other accessories for endoscopic diagnosis and treatment within the urethra, bladder, ureter, and kidney.

Technological Comparison

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The Stryker Video Ureteroscope employs the same technological characteristics as the predicate device. The device consists of a flexible working length attached to a handle containing an articulation lever and mechanism, allowing for the user to deflect the distal portion of the ureteroscope. The distal tip contains a video sensor and light fibers as well as the distal opening of the working channel through which patient fluids and materials can be passed. Both video ureteroscopes require the use of a powered console that processes video signals for display on an external monitor. The device is powered by the control console (Flexible Control Unit, or FCU). There is a single cable that connects the video ureteroscope to the console. The predicate device requires a separate light source with fiber optic cable to provide illumination, whereas the Stryker Video Ureteroscope contains an integrated LED light source that allows for visualization. However, the fundamental technology is the same, since light fibers carry the illumination through the scope, where it is emitted at the distal tip. The Stryker Video Ureteroscope's control unit's video output can be connected to documentation devices for video or photographic records, in a similar fashion to the predicate device's compatibility with Olympus' documentation devices.

Performance Testing

The Stryker Video Ureteroscope was tested for performance in accordance with design specifications and with the applicable performance standards. Biocompatibility was verified per ISO 10993-1:2009/Cor 1:2010 for patient contacting materials. Software was developed, tested, and verified per FDA guidance documents as well as IEC 62304:2006. Electrical Safety and Electromagnetic Compatibility were verified by testing to IEC 60601-1:1988/A1:1991/A2:1995 and IEC 60601-1-2:2007, respectively.

Bench performance testing performed on the Stryker Video Ureteroscope verifies the safety and effectiveness of the device per design specifications and acceptance criteria. Testing was performed to determine field of view, resolution, articulation performance, light output, leak integrity and other requirements based on the ISO 8600 family of standards. Please see Sec. 12 for a list of applied standards.

Conclusion

The submitted information in this premarket notification is complete, and based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the Stryker Video Ureteroscope raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kevin Potgieter, RAC
Senior Regulatory Affairs Analyst
Stryker Endoscopy
5900 Optical Court
SAN JOSE CA 95138

SEP 12 2012

Re: K121112
Trade/Device Name: Stryker Video Ureteroscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: August 29, 2012
Received: August 30, 2012

Dear Mr. Potgieter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Endoscopy

Device Name: Stryker Video Ureteroscope

510(k) Number if known: K121112

Indications for Use:

The Stryker Video Ureteroscope is designed to be used with a Stryker video system, monitor and other accessories for endoscopic diagnosis and treatment within the urethra, bladder, ureter, and kidney.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121112